SUBCHAPTER C—ADMINISTRATIVE DATA STANDARDS AND RELATED REQUIREMENTS

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

EFFECTIVE DATE NOTE: At 65 FR 50365, Aug. 17, 2000, subchapter C was added, effective Oct. 16, 2000.

Subpart A—General Provisions

Sec.

Subpart B—[Reserved]

AUTHORITY: Secs. 1171 through 1179 of the Social Security Act (42 U.S.C. 1320d–1320d–8), as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031, and sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)).

SOURCE: 65 FR 50365, Aug. 17, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 160.101 Statutory basis and purpose.

The requirements of this subchapter implement sections 1171 through 1179 of the Social Security Act (the Act), as added by section 262 of Public Law 104–191, and section 264 of Public Law 104–191.

§ 160.102 Applicability.

Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:

(a) A health plan.

(b) A health care clearinghouse.

(c) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

§ 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act.

ANSI stands for the American National Standards Institute.

Business associate means a person who performs a function or activity regulated by this subchapter on behalf of a covered entity, as defined in this section. A business associate may be a covered entity. Business associate excludes a person who is part of the covered entity's workforce as defined in this section.

Compliance date means the date by which a covered entity must comply with a standard, implementation specification, or modification adopted under this subchapter.

Covered entity means one of the following:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Group health plan (also see definition of *health plan* in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 (ERISA)(29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care, as defined in section 2791(a)(2) of the Public Health Service (PHS) Act, 42 U.S.C. 300gg–91(a)(2), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that—

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HCFA stands for Health Care Financing Administration within the Department of Health and Human Services.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies furnished to an individual and related to the health of the individual. Health care includes the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or

palliative care; counseling; service; or procedure with respect to the physical or mental condition, or functional status, of an individual or affecting the structure or function of the body.

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

(3) Procurement or banking of blood, sperm, organs, or any other tissue for administration to individuals.

Health care clearinghouse means a public or private entity that does either of the following (Entities, including but not limited to, billing services, repricing companies, community health management information systems or community health information systems, and ''value-added'' networks and switches are health care clearinghouses for purposes of this subchapter if they perform these functions.):

(1) Processes or facilitates the processing of information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of information into nonstandard format or nonstandard data content for a receiving entity.

Health care provider means a provider of services as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u), a provider of medical or other health services as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information means any information, whether oral or recorded in any form or medium, that —

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health insurance issuer (as defined in section 2791(b) of the PHS Act, 42 U.S.C. 300gg-91(b)(2), and used in the definition of *health plan* in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791 of the PHS Act, 42 U.S.C. 300gg–91(b)(3), and used in the definition of health plan in this section) means a Federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)). Health plan includes, when applied to government funded programs, the components of the government agency administering the program. Health plan includes the following, singly or in combination:

(1) A group health plan, as defined in this section.

(2) A health insurance issuer, as defined in this section.

(3) An HMO, as defined in this section.

(4) Part A or Part B of the Medicare program under title XVIII of the Act.

(5) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396 et seq.

(6) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(7) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(8) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(9) The health care program for active military personnel under title 10 of the United States Code.

(10) The veterans health care program under 38 U.S.C. chapter 17.

(11) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in 10 U.S.C. 1072(4).

(12) The Indian Health Service program under the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*).

(13) The Federal Employees Health Benefit Program under 5 U.S.C. 8902 *et seq.*

(14) An approved State child health plan under title XXI of the Act, providing benefits that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397 et seq.

(15) The Medicare + Choice program under part C of title XVIII of the Act, 42 U.S.C. 1395w–21 through 1395w–28.

(16) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)).

Implementation specification means the specific instructions for implementing a standard.

Modify or modification refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

Secretary means the Secretary of Health and Human Services or any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Small health plan means a health plan with annual receipts of $5 million or less.

Standard means a prescribed set of rules, conditions, or requirements describing the following information for products, systems, services or practices:

(1) Classification of components.

(2) Specification of materials, performance, or operations.

(3) Delineation of procedures.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For health plans established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for each health plan.

(2) For all other purposes, State means the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the exchange of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information exchanges:

(1) Health care claims or equivalent encounter information.

(2) Health care payment and remittance advice.

(3) Coordination of benefits.

(4) Health care claim status.

(5) Enrollment and disenrollment in a health plan.

(6) Eligibility for a health plan.

(7) Health plan premium payments.

(8) Referral certification and authorization.

(9) First report of injury.

(10) Health claims attachments.

(11) Other transactions that the Secretary may prescribe by regulation.

Workforce means employees, volunteers, trainees, and other persons under the direct control of a covered entity, whether or not they are paid by the covered entity.

§ 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.

(b) The Secretary may adopt a modification at any time during the first